DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 31, 2014

C.R. Bard, Inc.
Michele Davis
Regulatory Affairs Project Manager
8195 Industrial Blvd
Covington, GA 30014

Re: K142575
Trade/Device Name: Bard RiteCath Intermittent Urinary Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: EZD, EZC
Dated: September 11, 2014
Received: September 12, 2014

Dear Michele Davis,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P.
Lerner -S

for

Benjamin Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K142575

Device Name

Bard RiteCath Intermittent Urinary Catheter

Indications for Use *(Describe)*

The Bard RiteCath Intermittent Urinary Catheter is intended for use by adult and pediatric, male and female patients for draining urine from the bladder. Pediatric patients include neonates, infants, children and adolescents.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Bard Medical Division
C.R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

# 510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Bard RiteCath Intermittent Urinary Catheter 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

**Submitter:**
BARD Medical Division
C. R. BARD, Inc.
8195 Industrial Blvd.
Covington, GA 30014
Establishment Registration Number: 1018233

**Contact:**
Michele Davis, RAC
Regulatory Affairs Project Manager
Bard Medical Division
Tel: 770-784-6274
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**Date:**
September 11, 2014

**Subject Device:**
Trade Name: Bard® RiteCath™ Intermittent Urinary Catheter
Common Name: Urological Catheter
Classification Name: Urological catheter and accessories
Regulation: 21 CFR 876.5130
Regulatory Class: II
Primary Product Code: EZD
Secondary Product Codes: EZC

**Predicate Device:**
Legally marketed device to which substantial equivalence is claimed

- Bard RiteCath Intermittent Urinary Catheter, K133470
- Coloplast A/S Self Cath Catheter, K100878

**Device Description**

The Bard RiteCath Intermittent Urinary Catheter is a biocompatible, polyvinyl chloride (PVC) catheter used to drain urine from the bladder. The catheter consists of a funnel, shaft with two staggered eyelets and a tip. The tip is available in a straight or coude configuration. The tip of the catheter passes through the urethra into the bladder to allow urine to drain into the eyelets and then through the catheter shaft, exiting through the funnel. The catheter will be offered in multiple French sizes (6 – 18 Fr.), lengths (6", 10" and 16") and two tip designs (straight and coude). The product is ethylene oxide sterilized (per ANSI/AAMI/ISO 11135-1:2007, *Sterilization*

*of health care products – ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilized process for medical devices*). The catheter is for single use.

**Intended Use**

The Bard RiteCath Intermittent Urinary Catheter is intended for use by adult and pediatric, male and female patients for draining urine from the bladder. Pediatric patients include neonates, infants, children and adolescents.

The indications for use statement for the Bard RiteCath Intermittent Urinary Catheter is not identical to the predicate device; however, the differences do no alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use of urine drainage from the bladder (bladder drainage).

**Comparison of Technological Characteristics with the Predicate Devices**

The Bard RiteCath Intermittent Urinary Catheter has the same technological characteristics as the predicate devices. The subject and predicate devices are based on the following same technological elements:

- Catheter material
- Catheter length
- Tip configuration
- Drainage eye position
- Condition of use
- Sterilization

**Performance Data**

The following performance data were provided in support of the substantial equivalence determination.

<u>Biocompatibility</u>

The biocompatibility evaluation of the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "*Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices Part 1: Evaluation of Testing*'" May 1, 1995, and ISO 10993-1:2009 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."* The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Vaginal Mucosal Irritation

In addition a toxicological risk assessment for diisononyl phthalate (DINP) was performed per ISO 10993-17:2002 "*Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances*."

The subject device is considered mucosal contacting with limited exposure.

Nonclinical functional performance testing

Nonclinical functional performance testing of the subject device was performed in accordance with BS EN 1616: 1997 + A1:1999, *Sterile urethral catheters for single use*.

**Conclusions**

The Bard RiteCath Intermittent Urinary Catheter has the similar technological characteristics and is intended for the same use of draining urine from the bladder as the predicate devices. The subject device is substantially equivalent to the legally, marketed predicate devices and nonclinical test data demonstrates that the subject device is safe and effective.